TEMPLATE B

(Total ED greater than 0.3 rem and < or = 5 rem; adults)

This research study involves exposure to radiation from *(insert type of procedure or procedures)*. Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only. The total amount of radiation you will receive in this study is from (*insert maximum number*) injections (scans or repetitions) of (*insert quantity of radioactive material, in units of millicuries; or type of x-ray procedure).* The NIH Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving slightly greater than minimal risk and necessary to obtain the research information desired.

Using the standard way of describing radiation dose, from participating in this study, you will receive a total of *XX* rem to your (*insert highest-dosed organ*), *XX* rem to your (*2nd highest-dosed organ*), and *XX* rem to your (*3rd highest-dosed organ*). All other organs will receive smaller amounts of radiation.

Although each organ will receive a different dose, the amount of radiation exposure you will receive from these procedures is equal to a uniform whole-body exposure of (*insert effective dose value, in rem*). This calculated value is known as the "effective dose" and is used to relate the dose received by each organ to a single value. The amount of radiation received in this study is within the dose guideline established by the NIH Radiation Safety Committee for research subjects. The guideline is an effective dose of 5 rem (or 5,000 mrem) received per year.

For comparison, the average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from this research study is about the same amount you would normally receive in (*insert number)* years from these natural sources. If you would like more information about radiation and examples of exposure levels from other sources, please ask the investigator for a copy of the pamphlet called, *An Introduction to Radiation for NIH Research Subjects*.

(INCLUSION OF THIS PARAGRAPH IS OPTIONAL) The effects of radiation exposure on humans have been studied for over 60 years. In fact, these studies are the most extensive ever done of any potentially harmful agent that could affect humans. In all these studies, no harmful effect to humans has been observed from the levels of radiation you will receive by taking part in this research study. However, scientists disagree on whether radiation doses at these levels are harmful. Even though no effects have been observed, some scientists believe that radiation can be harmful at any dose - even low doses such as those received during this research.

One possible effect that could occur at these doses is a slight increase in the risk of cancer. Please be aware that the natural chance of a person getting a fatal cancer during his/her lifetime is about 1 out of 4 (or 25 percent). The increase in the chance of getting a fatal cancer, as a result of the radiation exposure received from this research study, is *(insert percent increase)*. Therefore, the total risk of fatal cancer may be estimated to increase from 25 percent to *(insert new rate)*. This change in risk is small and cannot be measured directly. Compared with other everyday risks, such as flying in an airplane or driving a car, this increase is considered slight.

(INCLUSION OF THIS PARAGRAPH IS OPTIONAL) One concern some people may have about radiation exposure is the effect on fertility or on the possibility of causing harm to future children (i.e., genetic risk). The doses you will receive in the study are well below the levels that affect fertility. In addition, genetic effects have not been seen in humans who have been exposed to radiation. The information on genetic effects currently available is based on animal experiments studies using doses of radiation much higher than the amount you will receive in this study.

Please tell your doctor if you have taken part in other research studies or received any medical care at the NIH or other places/hospitals that used radiation. This way we can make sure that you will not receive too much radiation. Consider x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant or breast feeding, you may not participate in this research study. It is best to avoid radiation exposure to unborn or nursing children since they are more sensitive to radiation than adults.